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REMARKS

The specification amendments above include mention of reference signs 108, 808, and 1804, so as to overcome the remaining drawing objections.

Claims 1-18 are pending in the application, with claims 1-11 having been withdrawn. By this amendment, claims 12-13 and 15-17 have been amended. Claims 19-22 have been added.

Claim Objections

Claim 17 was objected to as containing an informality. Claim 17 has been amended to overcome this objection.

35 U.S.C. §102(e) Rejection

Claims 12-18 stand rejected under 35 U.S.C. §102(e) over Haldimann, U.S. Pat. No. 6,428,576.

Regarding claims 12-18, Haldimann discloses a curable bio-compatible material. Claim 12 has been amended to overcome this rejection.

Further, Haldimann teaches *in-situ* curing of a liquid to form an implant (col. 5, lines 34-56). In Haldimann's disclosure, characteristics of the implant are developed by *in situ* curing, and are not characteristics of a device that is inserted.

Regarding claim 13, this includes the limitation of compacting the device before insertion. Haldimann discloses *in situ* curing of a material (col. 5, lines 34-56). The Examiner argues that expansion is inherent in the curing process (Office Action, page 5), but Haldimann does not mention any expansion on curing. Haldimann fails to teach the step of compacting a device before insertion. Curing is a chemically transformative process, and is generally not reversible. Hence, even if there is expansion on curing a material, this does not teach the compaction of a device before insertion. There is no suggestion that Haldimann compacts anything prior to spinal injection of curable materials, even if subsequent chemically transformative processes cause a later expansion of the cured materials. In any case, this expansion is not mentioned by Haldimann.

In the numerous examples provided, Haldimann illustrates his invention by describing the

injection of solutions into the spine. For example, Example 1 (col. 13, lines 24-35) describes the injection of an aqueous solution of collagen into a spine. Applicant's claim 13 includes the limitation of compacting a device before introducing the device into the spine. A solution cannot be compressed before injection. Further, a substance is not compacted by dissolving it in water. Haldimann teaches away from compaction by teaching the dissolution of injected materials. Haldimann discloses, as a preferred embodiment, the injection of a low viscosity solution (col. 7, lines 20-29) to facilitate injection. Haldimann states that the sealant "is implanted in a low viscosity liquid form, thus allowing the implanting material to penetrate into tears and micro-fissures" (col. 10, lines 14-19). A low viscosity solution implies a dilute solution. There is no suggestion that the volume of this solution is somehow compacted before insertion. Even if, as the Examiner claims, a cured polymer expands relative to an uncured material (a matter on which Haldimann is silent) a dilute solution of the uncured material is not a compacted version of the cured material. Hence, Haldimann fails to teach the limitations of claim 13.

Further regarding the issue of volume change on curing, U.S. Pat. No. 6,523,397 to Tosaki, entitled "Curing characteristics measuring apparatus and measuring method", describes an apparatus "wherein mechanism is provided for reducing volume of the sample chamber following volume contraction generated in curing process of the sample." The quotation is from the abstract of this patent, which is not relevant to Applicant's invention, but does illustrate that expansion is not inherent in a curing process.

Regarding claim 14, this claim describes the insertion of a device including a flexible screen or patch. Haldimann teaches the injection of a dilute solution, which later cures to form a seal. Haldimann uses phrases such as "The sealant of this invention ..." (col. 10, line 19), "the annulus sealing material" (col. 10, line 35), and further uses the term seal or sealant numerous times throughout the specification. For example, Haldimann states "In the practice of the present invention, for repairing defects of the annulus fibrosis, the sealant composition of this invention may be applied in several ways." (col. 3, lines 53-55). This does not contemplate anything but a sealant, though leaves open different embodiments regarding application methods. Hence, Haldimann fails to disclose a flexible screen. Further, as discussed above, Haldimann teaches the injection of a liquid. The "device" (using Applicant's claim language) inserted by Haldimann is a liquid solution. A liquid, by its nature, cannot possess a flexible

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screen or patch. Haldimann teaches in-situ curing of a liquid to form an implant, which the Examiner argues has the function of a patch. However, in Haldimann's disclosure, the implant is not inserted, it is formed *in situ* (col. 5, lines 34-56). Hence, Haldimann fails to teach the limitations of claim 14.

Regarding claim 15, this claim has been amended to apply to a method where the device inserted into the defect includes an anchor. Haldimann teaches the injection of a liquid which can be later be cured *in situ* to form a sealing material. The Examiner argues that the function of the sealing material formed on *in situ* curing is similar to that of an anchor. However, the injection of a liquid cannot be equivalent to the insertion of a device having an anchor, as a liquid cannot possess an anchor. The later cured material in Haldimann's disclosure may be secured by its cured shape, but the inserted liquid material does not possess an anchor. Hence, Haldimann fails to teach the limitations of claim 15. In Example 10 (col. 16), Haldimann discusses the implantation of pre-formed gels into the muscle of a rabbit. However, this work was carried out to investigate the toxicity of the gel. Spinal implants were stated to have been injected and "gelled in situ" (col. 17, line 21).

Further, claim 15, as amended, refers to an anchor that engages tissue proximate to the defect. The injected sealants of Haldimann flow into micro-fissures (col. 10, lines 14-19), but do not have an anchor that engages tissue proximate to the defect.

Regarding claims 16 and 17, claim 16 has been amended to be dependent on claim 13. The arguments presented above in relation to the patentability of claim 13 apply here also. Claim 17 is dependent on claim 16, and the same arguments apply regarding this claim.

New claims 19-22 have been added. Claims 19 and 20 are dependent on claim 14, and the arguments presented above in relation to claims 12 and 14 apply to these claims. Claims 21 and 22 are dependent on claim 15, and the arguments presented above in relation to claims 12 and 15 apply to these claims.

Based upon the foregoing, Applicant believes all pending claims are in condition for allowance. Questions regarding this application may be directed to the undersigned attorney at the telephone/ facsimile numbers provided.

Respectfully submitted,

By: _____

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